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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	BERGHOF ET AL
Serial No.	:	09/463,209
For	:	NUCLEIC ACID MOLECULE, TEST KIT AND USE
Filed	:	MAY 12, 2000
Examiner	:	JULIET C. SWITZER
Art Unit	:	1634

745 Fifth Avenue
New York, NY 10151

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**, on **October 14, 2004**.

Ronald R. Santucci, Reg. No. 28,988
(Name of Applicant, Assignee or Registered Representative)

Signature

October 14, 2004
Date of Signature

DECLARATION UNDER 37 C.F.R. §1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Kornelia Berghof-Jaeger (formerly Kornelia Berghof), declare and state that:

1. I make this declaration in connection with U.S. Application Serial no. 09/463,209. I am a co-inventor of this application and am familiar with its prosecution history, in particular, the Office Action mailed on May 14, 2004.

1. I make this declaration in connection with U.S. Application Serial no. 09/463,209. I am a co-inventor of this application and am familiar with its prosecution history, in particular, the Office Action mailed on May 14, 2004.
2. I am a citizen of Germany. As indicated on my attached *Curriculum vita*, I received a PhD degree from Technical University Berlin in 1990. I have been employed by Biotecon Diagnostics Gesellschaft fuer Biotechnologishe Entwicklung und Consulting mbH, the assignee of this application, since 1990. In view of my education and experience, I consider myself to be an expert in the field to which this application pertains.
3. I understand that claims 52-65 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kunsch et al, and Buchardt et al, for allegedly being obvious in view of the disclosure of these documents.
4. Kunsch et al is directed to the *Staphylococcus aureus* genome. The authors sequenced fragments of the *Staphylococcus aureus* genome and provide 5,191 individual sequences. The number of sequences together corresponds to the primary nucleotide sequence of the *Staphylococcus aureus* genome (see page 7, lines 7-9 of Kunsch). Due to this large and unmanageable number of sequences, the authors stored the sequence data on data storage means, which shall be used to identify commercially important fragments of the *Staphylococcus aureus* genome (page 7, lines 28-31 of Kunsch).
5. From the disclosure of Kunsch et al, the authors expect some of the genome fragments may be relevant for the etiology of diseases mediated by *Staphylococcus aureus* and that some of the fragments may lead to new ways for preventing or treating diseases (page 6, lines 29-32 of Kunsch).
6. Despite the fact that Kunsch et al have provided more than 5,000 sequence fragments of *Staphylococcus aureus*, the authors do not provide any teaching as to which particular fragment(s) is/are indeed specific for *Staphylococcus aureus*. This would have been absolutely necessary, since only species-specific fragments can be used to develop specific kits for diagnostics or medicaments for the treatment of *Staphylococcus aureus*-related diseases.

7. In my view, the teaching of Kunsch et al can be compared to the Human Genome Project, which aims at determining the entire sequence of the human genome. Although this task was completed some years ago, neither the scientific community nor pharmaceutical companies are currently in the position to use the genome to provide valuable medicaments or diagnostics for all human diseases. Fatal diseases, such as cancer, AIDS, or cardiovascular diseases still exist, because simply knowing the primary sequence of the genome by no means gives any hint to the function and usefulness of individual genes.
8. Due to the lack of any specific teaching as to the fragments or nucleotide positions that relate specifically to *Staphylococcus aureus* in Kunsch et al, it is my opinion that the skilled artisan would not have found Kunsch useful in designing probes and primers for specific *Staphylococcus aureus* detection.
9. Buchardt et al discloses peptide nucleic acids (PNAs) as novel DNA mimics wherein the sugar-phosphate backbone was replaced with an amino acid-based backbone (see Buchardt abstract). Therefore, PNAs are artificial nucleotides that can be incorporated into DNA or RNA for research purposes.
10. Simply combining the prior art knowledge of artificial nucleotides like PNAs with the entire sequence of *Staphylococcus aureus* consisting of millions of base pairs would not result in the present invention. Our knowledge on the existence of PNAs did not help us to determine which fragments and nucleotides in the *Staphylococcus aureus* genome were sufficiently specific for this bacterium for use as specific probes or primers.
11. Again, the situation can be compared to the Human Genome Project. Although the entire human genome is completely sequenced and skilled researchers today have more knowledge on artificial nucleotides like PNAs than was available some years ago, it is still not clear which exact fragments of the human genome are associated with deadly diseases. If having knowledge on PNAs is indeed sufficient for the combination with primary sequence data as the Examiner is alleging, no mysteries on the association of gene fragments with certain diseases should exist anymore.

12. In summary, it is my opinion that by simply combining the teachings of Kunsch et al and Buchardt et al, one skilled in the art would not have arrived at the present invention.
13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the US Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 13. October 2004

Kornelia Berghof-Jaeger

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Curriculum vita

Kornelia Berghof-Jäger, Ph.D.

She studied Biotechnology at the Technical University in Berlin and graduated with a degree in biotechnology. From 1984 to 1986 she worked as Scientist at the Oxford University in UK. Subsequently she worked on her Ph.D. work at the Technical University Berlin (Institute for Microbiology and Genetics) and at the Oxford University (Department of Biochemistry). In 1990, she was awarded her doctorate in biotechnology, Dr. Ing. In the same year she took part in the foundation of BioteCon GmbH, where she was appointed Managing Director and shareholder of the company. Besides this she was responsible for R&D of the company.
In 1998 she became Managing Director of BIOTECON Diagnostics GmbH with the responsibility for the R&D department.
Dr. Berghof-Jäger is member of numerous work and planning groups such as DIN (German Standardisation Organization), BGVV (Germans Food ans Health Authority), Dechema (German Association of Chemistry and Biotechnology).
She is chairman of the working group: „PCR for the detection of food borne pathogens in food" within CEN, the Europeaen Committee for Standardisation.

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